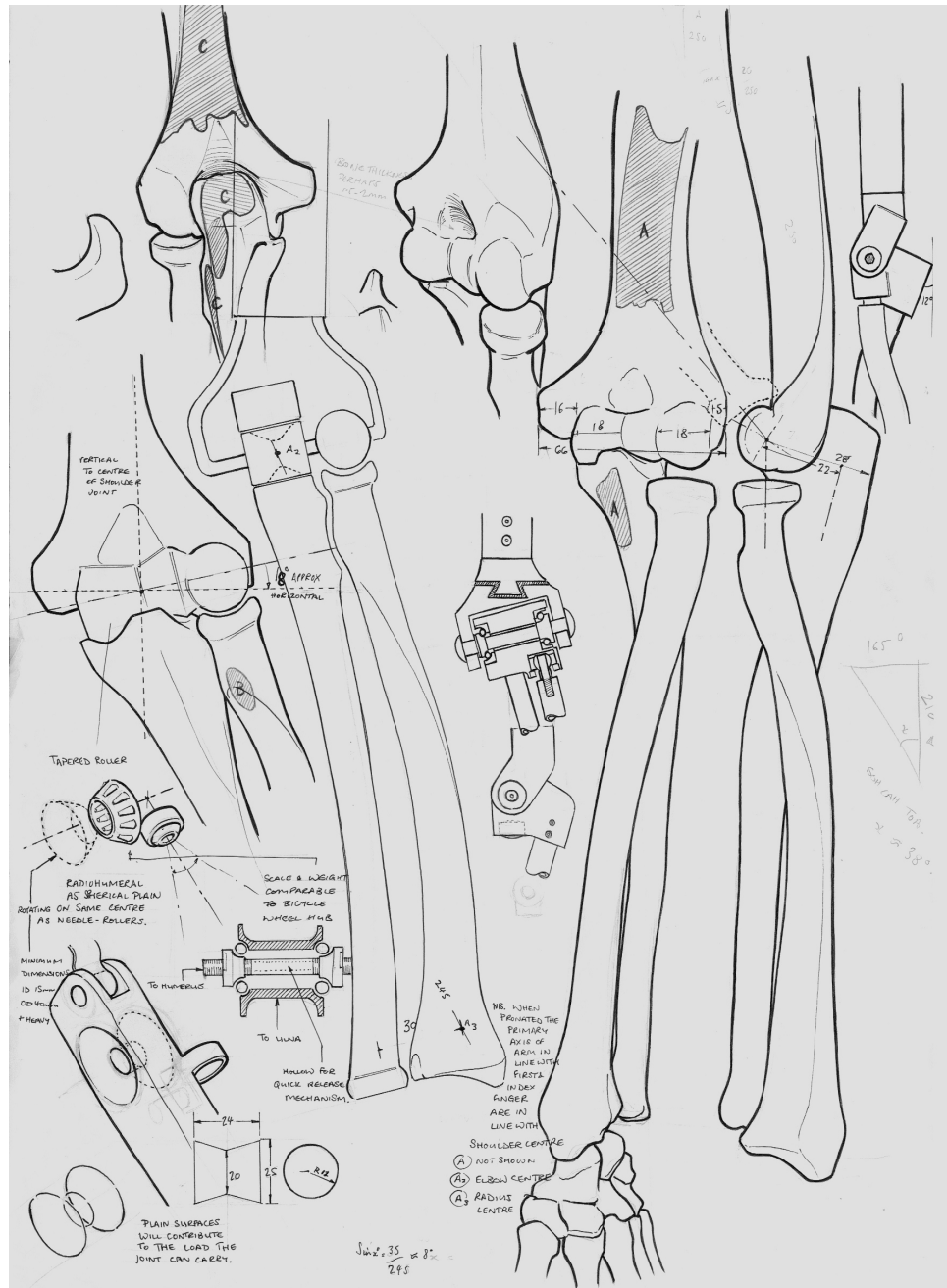


6. Development of an Anatomically Analogous Elbow Joint



A Sketch Sheet Used in the Development of the Model Elbow

The previous chapter showed the development of analogous joints permitting pronation and supination movements of a model forearm. Due to the combined nature of the articulation of the forearm and elbow flexion many of the principles elucidated in the development of the proximal radio-ulnar joint pertained to principles applicable for a model elbow joint. Therefore, it was considered that to successfully evaluate these principles a model combining elbow joint and forearm joints was needed.

To add to the anatomical analogy emphasis was placed on the production of a model elbow form that was close to the form of the distal humerus. Consequently, more complex prototyping methods were required than had previously been used.

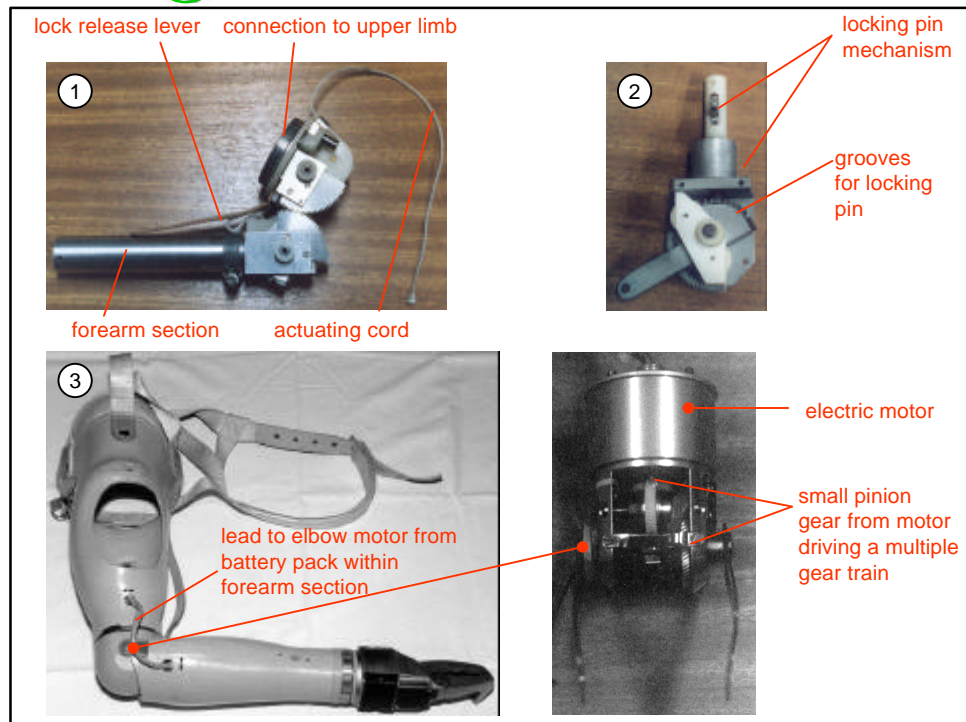
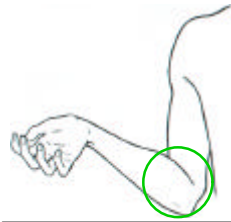
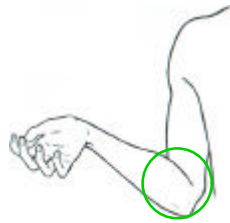


Fig 6.1 Prosthetic Elbow Components

Prosthetic replacement elbows are essential to the amputee, as the function of the elbow is crucial for feeding activities (Kapandji 1982). The loss of the function of the elbow joint rather than any other joint has been indicated as jeopardising independent living through making it impossible to carry out activities of daily living (Stanley and Kay 1998).

Figures 6.1(1) and (2) show two components from body-powered elbows. Figure 6.1 (1) shows two gears where the movement is controlled by a chord. This arrangement of the gears allows a range of movement of around 180 degrees flexion, whilst minimising the amount of excursion needed from the actuating cord (Banerjee 1982). Minimal actuating cord excursion is necessary as the motivating movement of bi-scapula adduction only produces limited cord excursion, part of which may also be required to operate the jaws of the split hook (Banerjee 1982). Figure 6.1 (2) shows a locking mechanism used in prosthetic elbows. 'Locks' are used to maintain levels of flexion of the elbow whilst requiring no further physical effort from the amputee to maintain this position. The lock shown achieves this function through a pin falling into grooves machined around a gear. Once locked, the mechanism (1) requires the contralateral arm to operate a release lever on the forearm section of the prosthesis. Powered locking mechanisms have been developed for electrically powered elbows, working on a similar to the mechanism of (2) (Jacobsen et al 1982).

Powered components such as (3) commonly consist of an electric motor in the humeral section, with a gear assembly at elbow level that reduces the high speed low torque rotations of an electric motor to lower speed higher torque movements suitable for flexion of the prosthetic elbow. These devices are assembled to minimise their bulk and so allow for a range of humeral lengths to be accommodated in a single modular design (Ibbotson 1999). However, the large amount of gearing required make these components comparatively heavy at around 2/3 kg (Otto Bock 2000).



Development of an Anatomically Analogous Elbow Joint Translating Design Principles

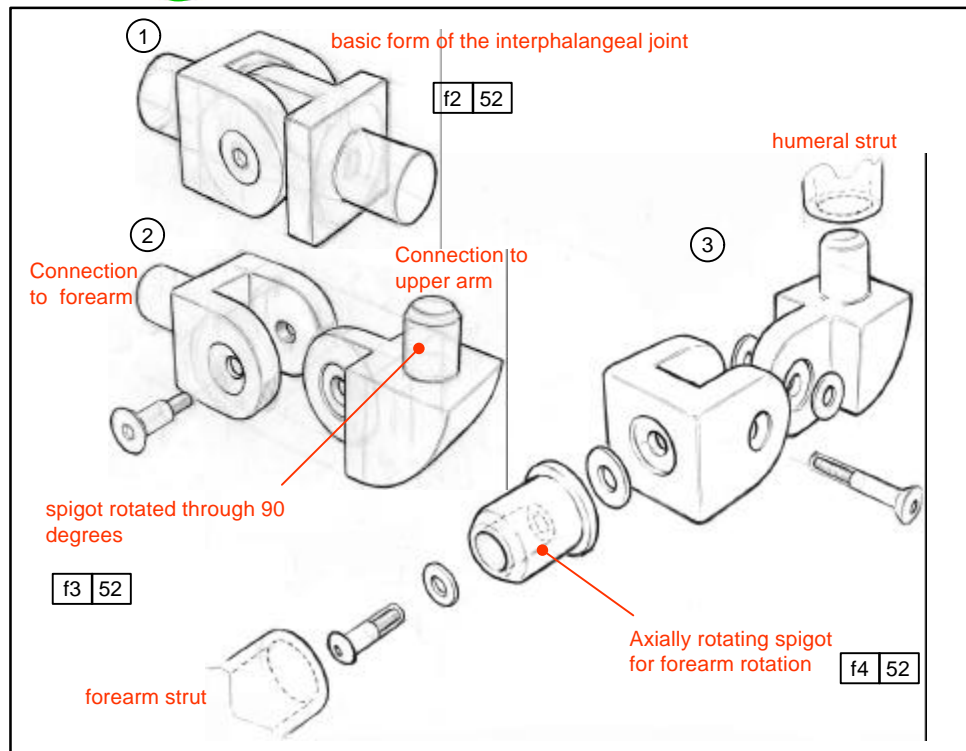


Fig. 6.2 Translating Design Principles from the IP Joints to the Elbow

It was found that the development of the elbow could not be separated from the development of the articulations of the forearm. Therefore, sketchbook idea development focussing on the elbow also includes ideas for the articulations of the elbow that include flexion / extension of the forearm.

Initially articulations for the elbow were considered using mechanical principles that had already been elucidated in the development of the interphalangeal joints (chapter 3). This was considered appropriate since initial observation of the motion of the intact human elbow suggested that the articulation of the elbow was similar to that of a simple uniaxial rotation. Additionally, the rotary movement of the forearm appeared to be similar to that of an axial rotation about a central spigot. Consequently, the initial sketch ideas above focused on implementing the simple IP joint principles of articulation to the articulations of the forearm and elbow. Figure 6.2 (2). shows how the form of the basic interphalangeal joint (1) might be changed by rotating one of the spigots through 90 degrees to enable this type of joint to possess the to correct range of movement for an elbow joint.

Comparison of the form of these ideas to that of the anatomy, showed that they differed considerably from the original anatomy. The most obvious deviation being that the human forearm contains two bones, whereas the proposed forearm articulation consists of a single strut. Additionally, whilst a single axially rotating strut might approximate the range of movement of the forearm anatomically the arrangement of struts and joints is quite different (chapter 5). Therefore, to obtain a closer mechanical analogy of these joints observational drawing studies were undertaken; firstly, for the forearm joints and subsequently for the junction of the forearm joints with the humerus which is discussed in the following pages.

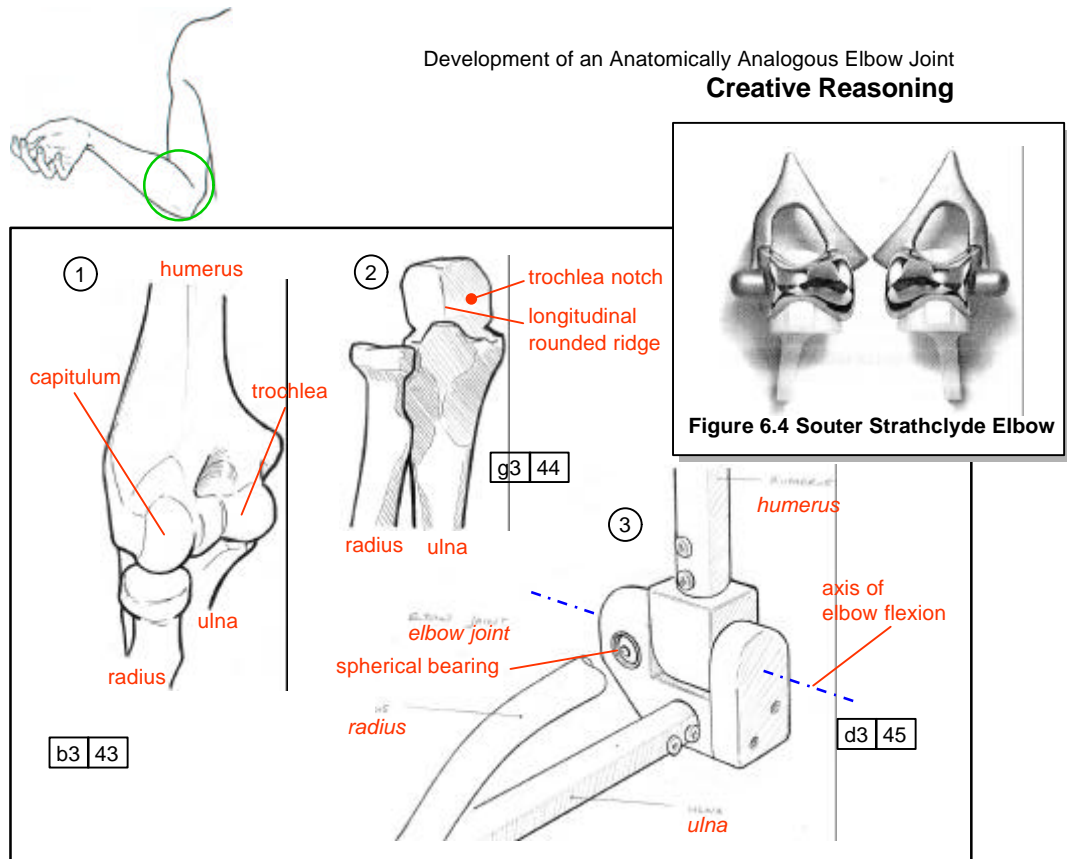


Fig 6.3 Observational Drawings of the Skeletal Elbow

Figure 6.3 (1) shows an observational drawing of a skeletal right arm. This can be determined from the position of the capitulum and trochlea on the humerus. The capitulum is a partial spherical surface (Kapandji 1982) on which the radius bone articulates. The capitulum is lateral to the trochlea when the humerus is facing anteriorly (facing front).

At this stage a review of implantable elbow prostheses was undertaken to ascertain their appropriateness for an analogous model. It was found that all commercially available components focus on the trochlea to ulna articulation (Betts 1998). The Boimet Ltd Kudo Elbow and Souter Strathclyde Elbow (figure 6.4) closely reproduce the form of the trochlea from biocompatible metals such as titanium (Biomet 1990, Howmedica 1990). The form of the ulna's trochlea notch in the Souter Strathclyde Elbow is moulded in high density polyethylene (Howmedica 1990). The bones of the elbow are connected within the body by ligaments (Guyot 1990). To the sides of the elbow joint, are medial lateral ligaments and to the front and reverse an anterior ligament and posterior fibres, as well as additional oblique ligaments (Guyot 1990). Both the implants discussed require that the ligaments remain intact, as the articulating surfaces of the implant's ulna trochlea notch and trochlea do not extend far enough around one another to support loads (Betts 1998). There are elbow implants that are linked together, such as the Alivium Stanmore Total Elbow Replacement (Zimmer 1990). This component possesses a convoluted form, but kinematically it is a simple uniaxial articulation (Betts 1998). However, it is made of solid steel components and was therefore considered too heavy for an analogous model. Additionally, a joint for the capitulum to radius articulation was also needed.

Experience in the development of the MCP joint (figure 4.3) showed that sketch ideas using an analogy for ligaments surrounding the joint may be overcomplicated (figure 4.3 (4a)). Consequently, sketch ideas were developed focussing on mechanically connecting the trochlea and ulna, initially by a simple hinge (3). Sketch (3) shows a spherical bearing as analogy of radius to capitulum articulation and ulna to trochlea.

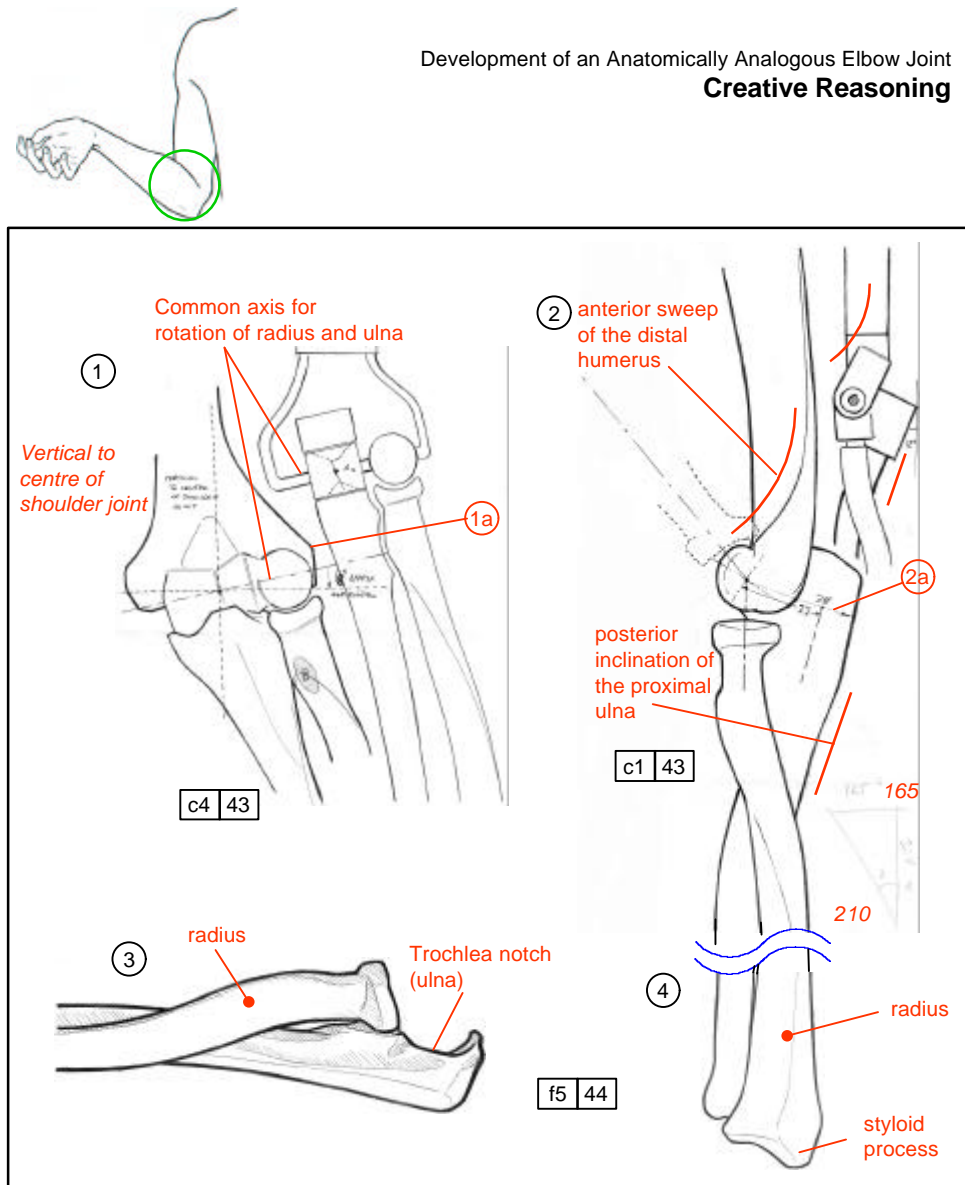


Fig 6.4 Observational Drawings of the Distal Humerus

Continued observational drawing highlighted that the rotation of the ulna and radius appear to lie on a similar axis across the humerus (1), a finding supported by anatomical literature (Kapandji 1982). The process of observational drawing also indicated that the distal portion of the humerus sweeps anteriorly (2). The humeral sweep appears matched by a posterior inclination of the proximal ulna (2). The trochlea notch on the anterior surface of the ulna (3), offsets the main shaft of the ulna (2a), enabling the unimpeded range of movement of the elbow to typically 145 degrees (Smith et al 1996). To determine the range of elbow flexion of an average male, approximate measurements of ultimate flexion angle were taken from one of the researchers whom had been used as the basis of measurements in previous joint development. Several points were chosen on the arm that were both easily determined from palpation, and also appeared relatively unchanged during flexion and extension movements of the elbow. The styloid process (4), lateral epicondyle (1a) and a position where the deltoid meets the humeral shaft were determined from palpation and marked on the skin. Measurements were then taken between these points with a rule accurate to 0.5mm. A measurement was then taken on full flexion of the arm between the styloid process and the insertion of the deltoid. Simple trigonometry revealed estimated an acute angle of 34 degrees. As no hyperextension of the elbow could be seen, the range of movement of the researchers elbow was estimated as $180 - 34 = 146$ degrees.

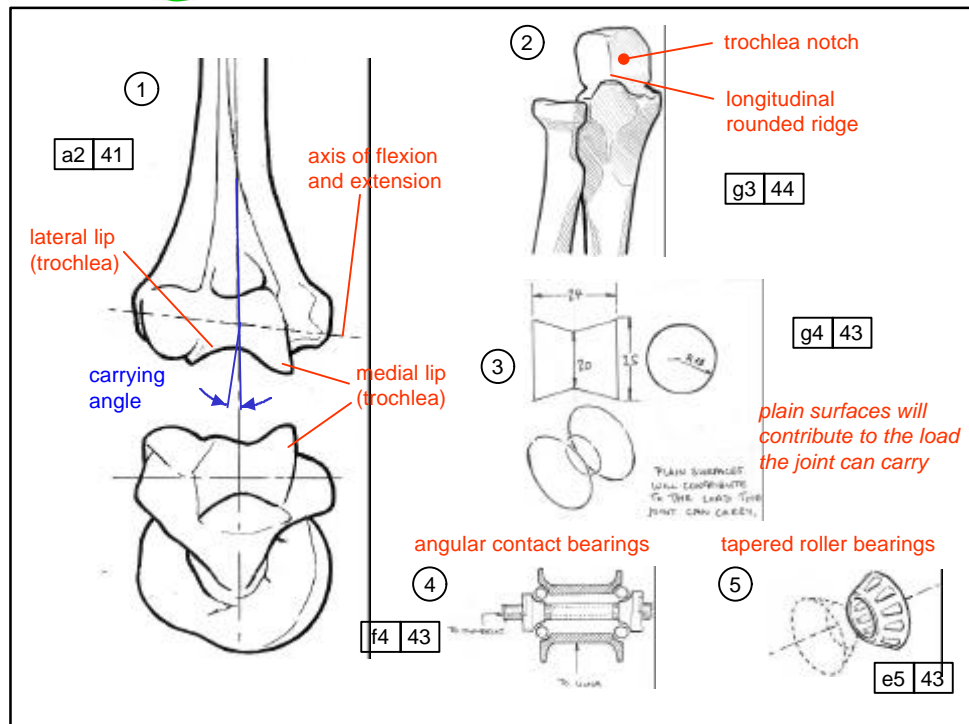
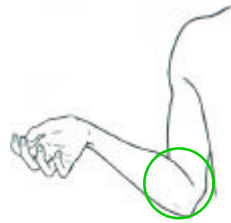


Fig 6.5 Observational Studies of the Trochlea

Further drawing studies of the trochlea indicated that the medial lip of the trochlea appeared lower than the lateral lip. Literature review states that this is an indication of the 'carrying angle' (Smith et al 1996). The carrying angle has been defined as the acute angle measured between the extended forearm and a line extrapolated from the long axis of the humeral bone (Smith et al 1996). There is wide variation in the magnitude of the carrying angle in individuals, with the carrying angle reported greater in women than in men, ranging between 5 and 19 degrees (Smith et al 1996). The carrying angle of one of the male researchers was measured by extending the arm onto a piece of card. Straight edges were then aligned against the medial edges of the lower and upper arm and lines scribed against the straight edges. These lines were subsequently measured using a protractor accurate to 1 degree, and the carrying angle estimated at 13 degrees. No clear function has been identified for the carrying angle (Smith et al 1996), however, cosmetically the possession of a carrying angle may be significant as it can be observed in the extended arm of females. The carrying angle is not reproduced in current prosthetic elbows, as flexion occurs along an axis perpendicular to both the long axes of the upper and lower arm sections.

Observational studies of the trochlea notch highlighted, what is referred to as, a longitudinal rounded ridge (Kapandji 1982). Initially, it was considered that the form of the trochlea and trochlea notch function to resist both axial and thrust forces. Therefore, the trochlea was considered analogous to angular contact bearing races (4) or tapered roller bearings (5), which are arranged to resist similar loading. The observational studies were followed by palpation of skeletal anatomical models. It was found that the ulna could be palpated laterally against humerus. This was initially considered due to absence of the cartilaginous tissue in the model, however, literature review indicated that a lateral movement at this joint may occur during pronation and supination (Amis 1990) (Chapter 5).

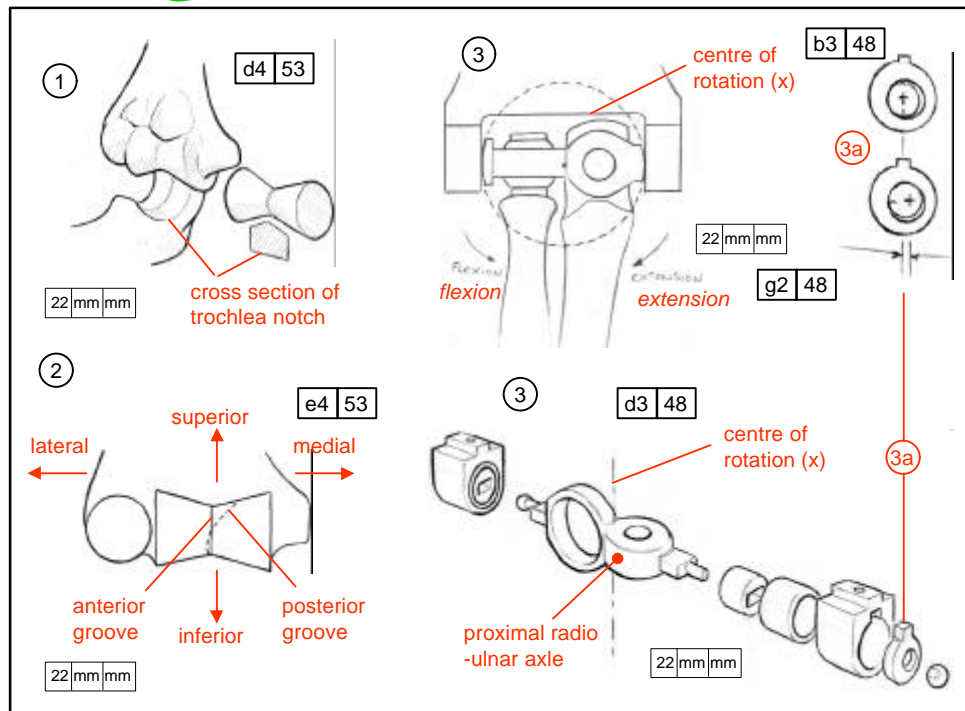
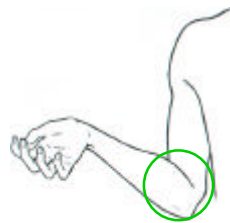


Fig 6.6 Initial Sketch Ideas for Carrying Angle Mechanisms

More extensive review of anatomical literature indicated that the carrying angle may vary with angle of flexion of the elbow (Kapandji 1982). Kapandji's theory states the mechanism for carrying angle change is by the close contiguity of the trochlea notch to the trochlea (Kapandji 1982). Sketch (1) shows how a pointed section of the trochlea notch could be imagined being guided by the bobbin section of the trochlea. Kapandji states that the trochlea instead of the of possessing simple groove, most commonly possesses a groove running directly superiorly to inferiorly (top to bottom) on anterior view (front) and helically, superior-medially, to inferior-laterally on the posterior view (Kapandji 1982). Kapandji indicates this has the effect of causing a lateral carrying angle in the extended arm, whilst when the elbow is flexed the forearm aligns with the upper arm eliminating the carrying angle.

The possession of a clear carrying angle might have cosmetic benefit when viewing the extended arm. However, the cosmetic and functional significance of a changing carrying angle is unclear (Smith et al 1996). More recent anatomical literature report different methods of measuring the carrying angle indicating that uncertainties as to whether the carrying angles diminishes during flexion, or remains constant (Stanley and Kay 1998). It was considered from this evidence combined with reported individual variations of carrying angle (Kapandji 1982); that a first model elbow should possess a constant carrying angle. However, further iterations of the model might include the mechanism for a changing carrying angle if evaluation of the model joint indicated its absence detrimentally effected appearance or function.

At this stage in the development of the analogous elbow the parallel investigation into pronation and supination of the forearm (Chapter 5) had resulted in a proximal radio-ulna axle. A mechanism (3) was proposed to permit this axle to rotate about a centre (x) using cams (3a) to cause a lateral rotation on extension and medial rotation on flexion. This complexity of the mechanism made it undesirable of for model prototyping.

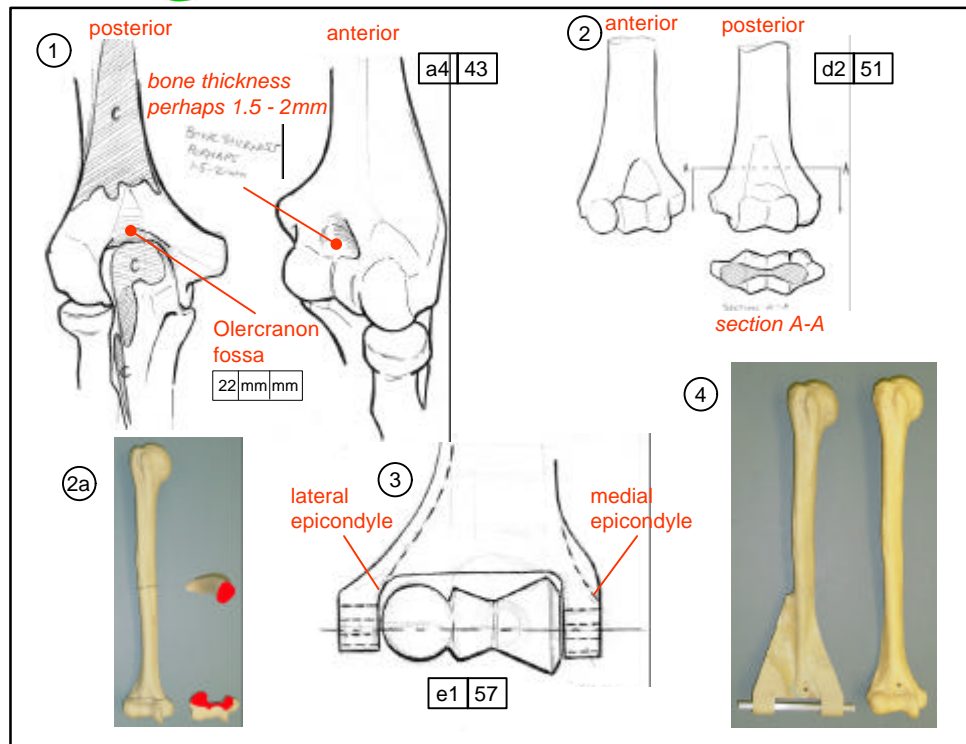
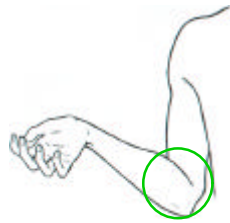


Fig 6.7 Observational Drawing of the Distal Humerus

Observational drawing was combined with moulding techniques to further investigate the form of the distal humerus. Observational drawing indicated that the distal humerus flares outwards becoming wider rather than deeper in anterior view. Drawing studies indicated depressions immediately above the trochlea on both anterior and posterior surfaces (a). Anatomical literature refers to these depressions as the olercranon fossa (Kapit and Elson 1993).

To determine the thickness of the humerus at this point a resin copy of a humeral bone was cross sectioned. To make the resin copy a silicone rubber mould was made from a skeletal model humeral bone. A resin copy of the humerus was then taken from the mould and cut transversely to determine its cross section at different points along its length (2a). Towards the middle of the humerus its section is approximately circular, towards the capitulum and trochlea the form divides into two over the trochlea (2). As it was considered that an analogy of the trochlea and capitulum should rotate on a common axle, the indication of the division in the form was 'exaggerated' in development sketches (3) to 'fork' like forms to hold the common axle. Another resin humerus was taken from the mould and a shaft fitted through it at the approximate centre of the capitulum and trochlea. Further resin was added to visually ascertain the effect of using the medial and lateral sides of the distal humerus as supports for the proposed shaft (4). It was found that little resin was needed to build up an adequate support for a 6mm shaft on the medial side, as this corresponded with the medial epicondyle (d). However, more material was needed on the lateral side, as this epicondyle is much less prominent from the articulating face of the capitulum (3). Despite this prominence the approach was still considered appropriate, as from observation of the intact arm the medial epicondyle appeared much closer to the outer profile of the arm. Whereas, a slight prominence on the lateral epicondyle might be 'masked' by the bulk of the brachioradialis and extensor carpi radialis longus muscles.

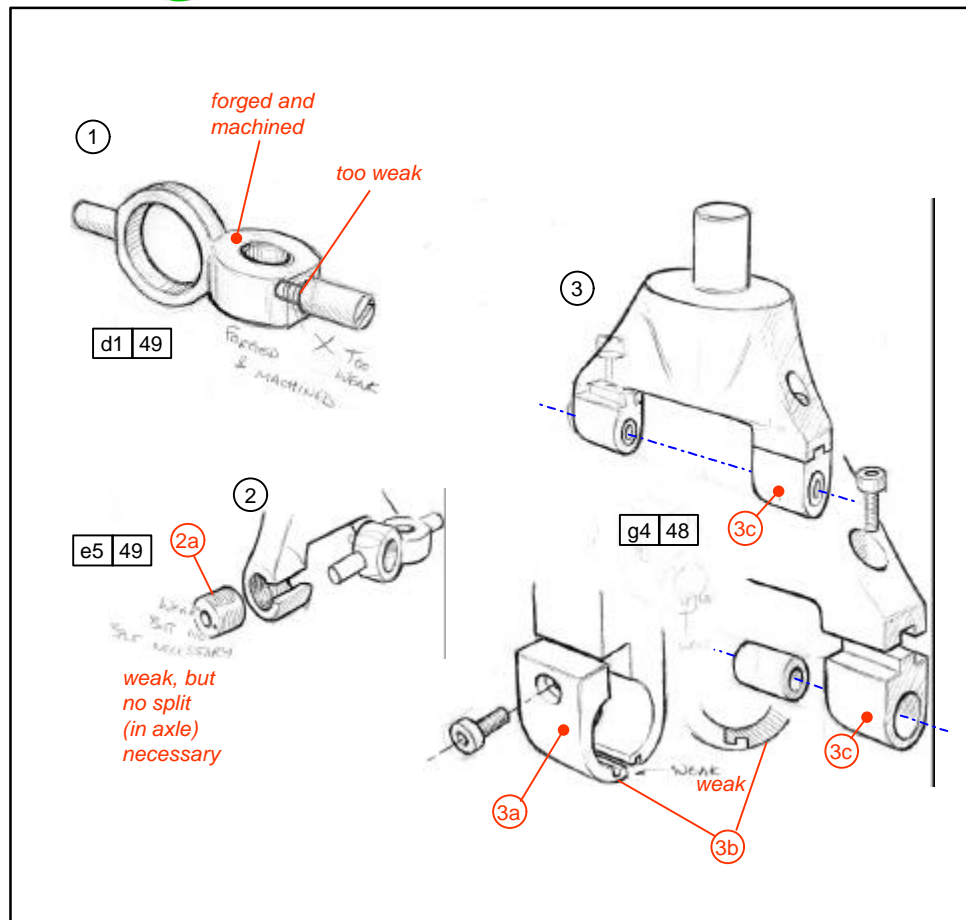
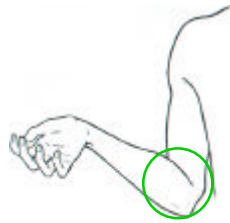


Fig 6.8 Inserting the Proximal Radio-Ulnar Axle

Continued development of the humeral component focussed on a means of inserting the radio-ulna axle. It was considered that the axle component should be machined from a single forged steel billet for strength. Initially, splitting the axle had been considered to insert it into the elbow fixture, however, latterly splitting the axle was thought to compromise its strength (1). Instead, sketch (2) shows a how a split in the humeral component might permit access for the axle shafts. Plain axle bearings might then be threaded into the humeral component to fix the axle in place (2a). Having an incomplete cylinder to hold the axle bearing was considered too weak. Sketch (3a) shows how the split might be configured using a separate screw fixed component (3a), incorporating a mating joint to increase strength. Both sketch ideas (2) and (3a) were considered to compromise strength; instead sketch (3c) shows the favoured solution, separating the component along the axis of elbow flexion.

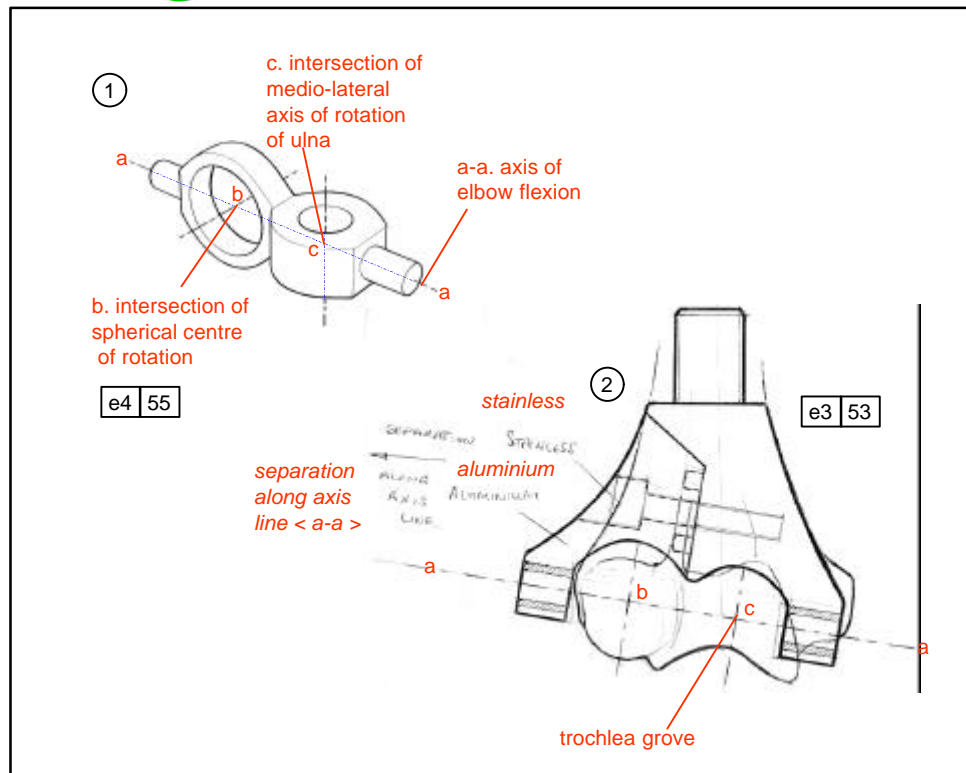
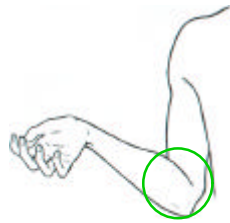


Fig 6.9 Location of the of Elbow Components

In the development of the proximal radio-ulna axle the ulna to capitulum articulation was considered a spherical articulation, equivalent to that permitted by a spherical bearing. This was found consistent with existing anatomical literature (Kapandji 1982, Smith et al 1996, Kapit and Elson 1993). More speculatively, the trochlea to trochlea notch was considered to possess a medio-lateral articulation (1) (Chapter 5). Subsequent designs for the humeral section of the elbow were developed using an observational drawing of the humerus as an underlay (2). During this process care was taken to position the proximal radio-ulna axle where intersections of the axes of rotation appeared close to those on the distal humerus. As the capitulum is considered a partial spherical surface, an approximation of the centre of rotation was found by matching a circle with similar diameter and known centre to the periphery of the capitulum (2 - b). The medio-lateral articulation of the trochlea to trochlea notch articulation was estimated at the centre of what is referred to as the trochlea groove (Kapit and Elson 1993) (2 - c). The positioning of the proximal radio-ulnar axle provided further resolution of the proximal aspect of the elbow component and indicated that further resolution of the form of the proximal aspect of the elbow component was necessary.

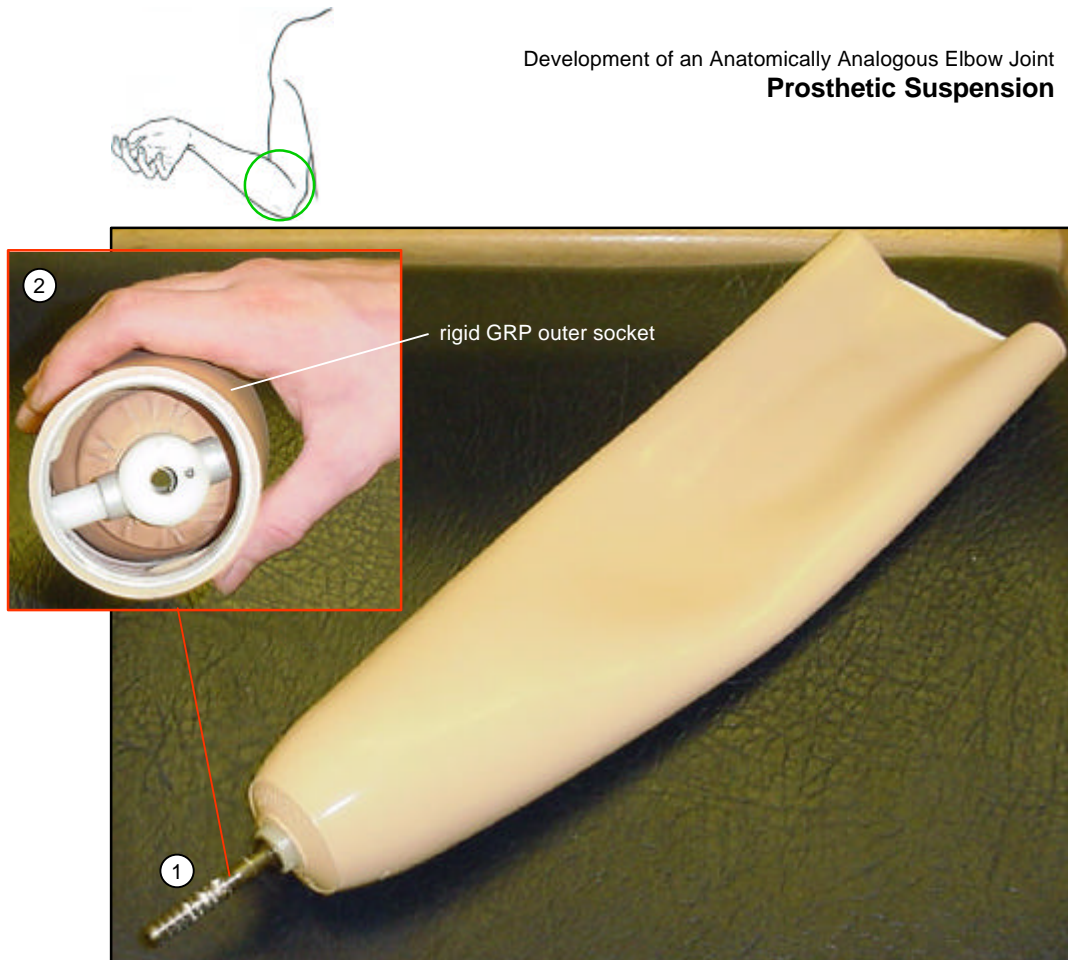


Fig 6.10 The Commercial ICEROSS Prosthetic Suspension System

The proximal end of the elbow component required a fixture that permitted the elbow to be attached to a suspension mechanism. Review of some of the existing suspension devices for upper-limb prostheses was done at the Centre of Mobility and Specialised Rehabilitation at the Northern General Hospital, Sheffield. An interview with V. Ibbotson a Senior Occupational Therapist at this centre indicated that the more successful suspension methods relied on donning of the suspension system separately to the prosthesis (Ibbotson 1998). Figure 8.10 shows the ICEROSS suspension socket. In this method of suspension an air tight soft silicone socket is first rolled on by the amputee. Moulded into the distal end of the socket is either a bayonet fitting (1) or piece of cord. The rigid glass reinforced plastic (GRP) prosthetic socket is then pushed onto the silicone socket. The GRP is secured to the silicone either by the mating of the bayonet with a clip (2), or by the cord being wrapped around a capstan on the exterior of the GRP shell. Using the cord method the silicone socket is pulled into the GRP socket protecting the distal end of the remaining limb (Ibbotson 1998).

All the observed suspension systems rely on a rigid prosthetic shell to stabilise the prosthesis. The aspects of the existing devices that appeared of benefit to a future mid-humeral prosthetic device were; donning the suspension system separately, and protecting the distal section of the amputees arm. Connecting the prosthesis to the suspension system was observed to be easier with the bayonet clip when carried out with only a single arm. Reported less favourable features of existing suspension systems were; the lack of circulation of air around the socket requiring high levels of hygiene of the amputee (McCurdie et al 1997) and the rigidity of the GRP socket (Ibbotson 1998).

Development of an Anatomically Analogous Elbow Features for Potential Suspension

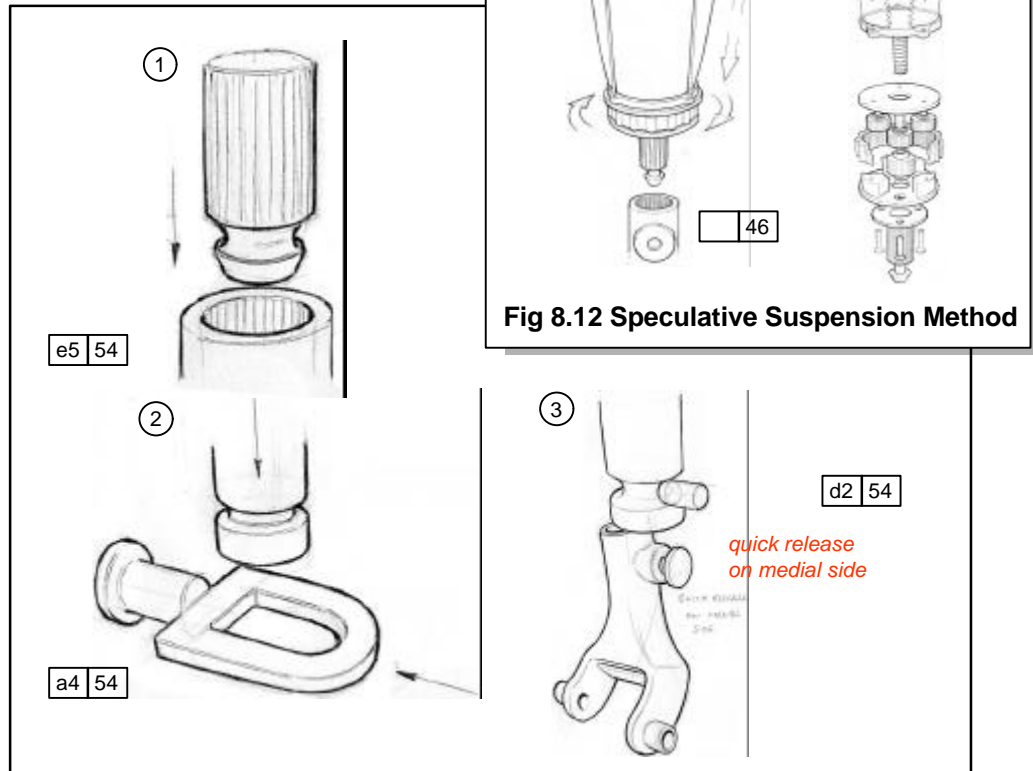
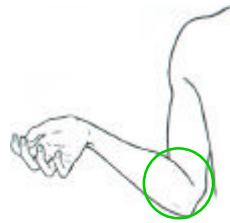
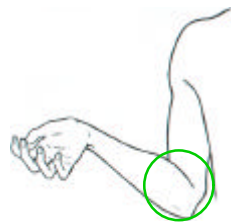


Fig 6.11 Consideration of Suspension Methods

In view of earlier finding of the focus group the integration of a rigid exoskeletal shell suspension method into the design principles of a future prosthesis was inappropriate. Additionally, it was thought that an exoskeletal approach would significantly divert from the method of design by analogy to the human anatomy. Instead what were considered to be the most beneficial aspects of existing suspension methods were used. The interview with V. Ibbotson indicated that donning of a separate suspension system was preferable to the amputee. Consequently, a peg projecting from a future suspension was considered a simple means of mating a suspension system to the elbow component (1).

From attendance at many amputee meetings it has been observed that it was difficult for the amputee to consistently ensure the suspension system has the orientation with respect to the long axis of their remaining limb. Therefore, angular adjustment was incorporated into the elbow fixture through splines on in the bore of the elbow component (1). Connection of existing prostheses onto the silicone socket was reported as most easily achieved through a bayonet and sprung quick release similar to sketch (3). Therefore, a bayonet form was applied the distal end of the peg, and a sprung quick release was fitted to the medial side of the casting. The medial side was chosen as it was considered less vulnerable to accidental release than placement on the lateral side (4). A future suspension system was sketched purely to visually explore the consistency of securing the endoskeletal model arm by a 'soft' exoskeletal method to the amputee. The design speculates that a socket might be made from an inextensible braid and three corset type ribs. The sketch proposes the braid be secured to the limb by extending the braid along its long axis once the limb is inside the braid. However, the detail of this design is not the subject of this research.



Development of an Anatomically Analogous Elbow Joint Features for Potential Actuation

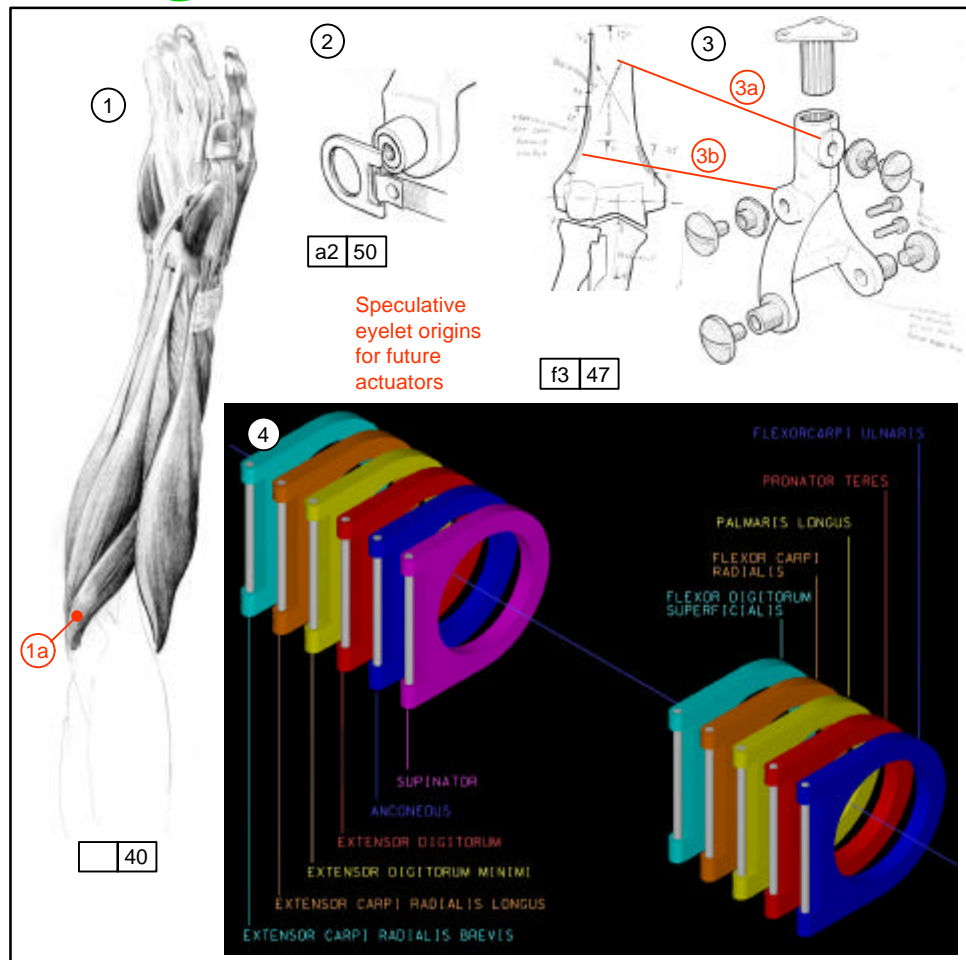
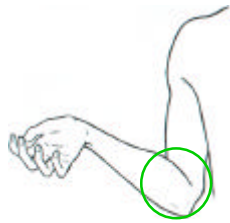


Fig. 6.12 Extrinsic Muscle 'Origins'

Wire 'tendons' were used to activate the digits of the model hand. A literature review on the elbow suggested that many of these extrinsic tendons 'originate' at the elbow (Kapit and Elson 1993). Further observational drawing from anatomical models marked with muscular attachment points elucidated that many of the extrinsic flexor muscles of the hand originate from the medial epicondyle of the humerus, whilst the extrinsic extensor muscles originate from the lateral epicondyle; an observation supported by the anatomical literature (Kapit and Elson 1993). It was thought appropriate that an anatomically analogous model elbow should closely reproduce these 'origins'; just as many of the 'insertions' had been reproduced on the model hand. Observation of the extrinsic musculature of cadavers combined with observation of muscular anatomical models (1) show these muscles to overlap one another as they approach their origin on the distal humerus (1a). Consequently, simple eyelet-type origins were designed to fit onto cylindrical bearings (2), concentrically arranged with the main axis of elbow flexion on the medial and lateral sides (3). Observational drawing also highlighted that origins for the muscles of brachialis (3a) and brachioradialis (3b) are within the space occupied by the elbow component, therefore, two further similar 'origins' were provided. The suspension peg prompted questions of future suspension methods, similarly this stage focussed questions about the appropriate actuation strategies. Consequently, researchers working in the field of novel actuators were contacted (Della Santa 1997).



Development of an Anatomically Analogous Elbow Joint Design Principles

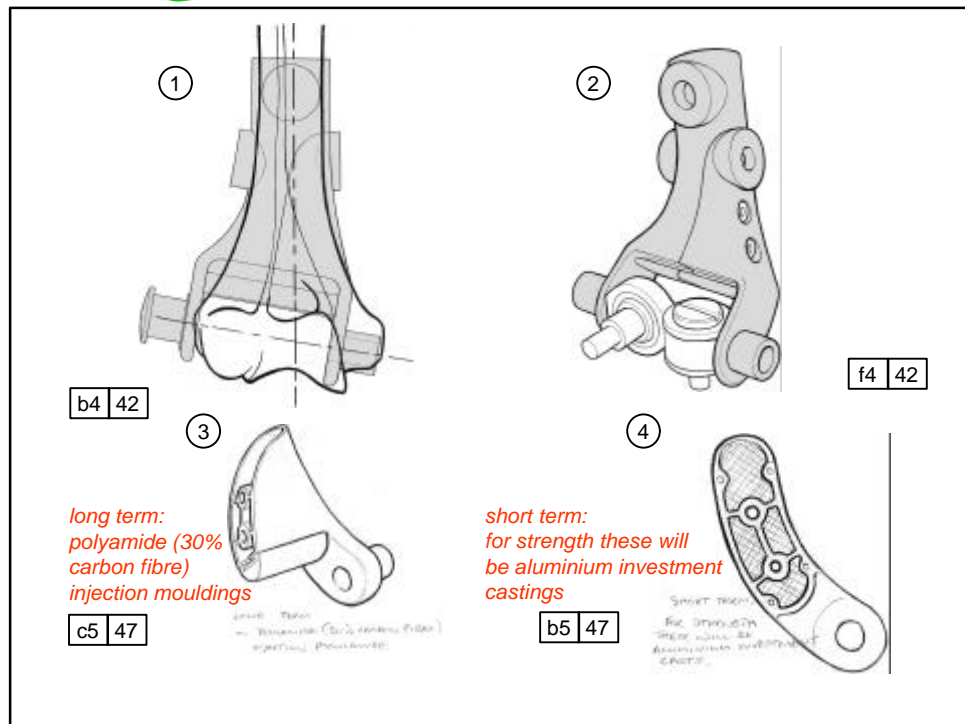


Fig 6.13 Proposed Design

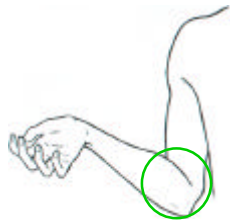
Following the evaluation of the form of the model finger joints (Evaluation by Dr. Williams chapter 6) the form of the analogous elbow was designed to be much more complex and contoured than previous joint designs.

Approximating the contours of the distal humerus resulted in a design of relatively large volume (1, 2). The comparatively large weight of existing myoelectric prostheses is indicated as a major factor in their indiscomfort (Kejlää 1993). Consequently, to reduce weight but both retain these contours and retain comparative strength it was thought the components form should be a shell or skin form (Gordon 1978) (3, 4).

Findings from separate US research using pneumatic muscles to flex a model elbow show that friction against these actuators, when arranged in an anatomical manner, severely limits their efficiency (Hannaford et al 1995). Therefore, a smooth outer surface was proposed for the elbow component to reduce friction against devices used for actuation. Materials were chosen that had good bearing properties whilst retaining rigidity (3).

The proposed design includes two securing machine screws. Two screws were proposed both to increase clamping force between the two forms but additionally, to ensure the correct alignment of the two bores that permit articulation of the proximal radio-ulna axle.

Features such as lightness of weight and a smooth contoured form through the production of a 'skin' were prioritised in the production of the model. It was considered that a casting technique would be the most appropriate for prototype production, as the chosen plastic requires injection moulding equipment, unsuited to prototyping. Consequently aluminium was considered a suitable substitute material for a lightweight rigid form that could be highly finished.



Development of an Anatomically Analogous Elbow Joint Prototype Production

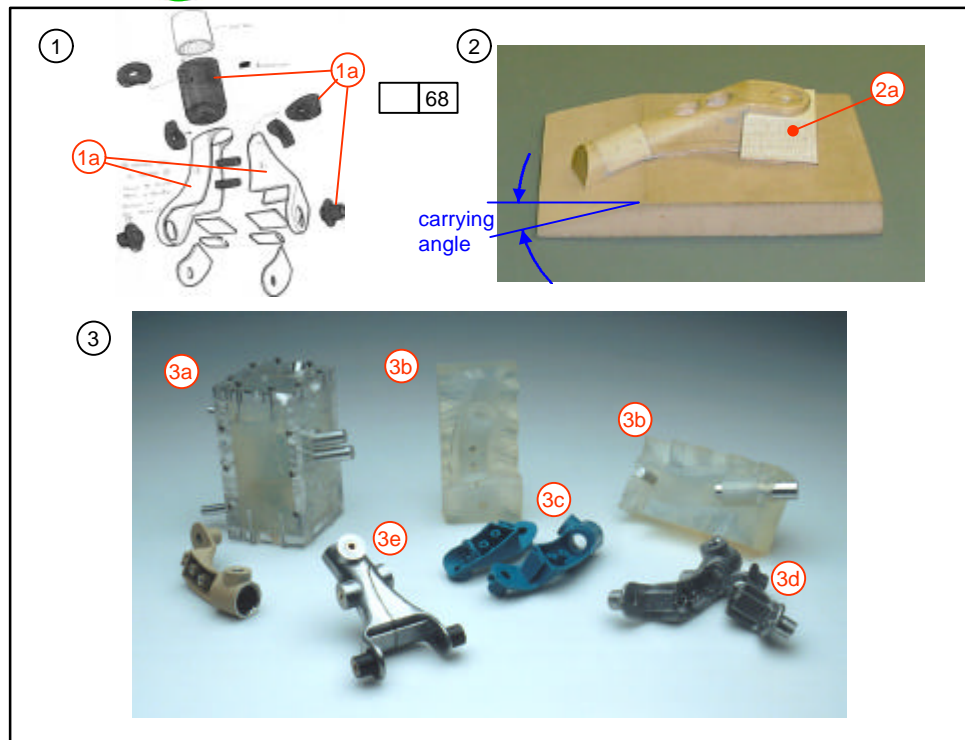
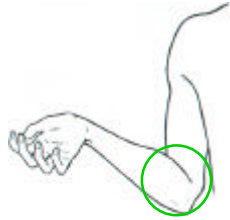


Fig 6.14 Prototype Manufacture

Using a casting method requires the production of a master 'pattern'. The highly complex form of the elbow appeared unsuitable to conventional or CNC machining processes used in the production of previous designs. Consultation with a skilled pattern maker indicated that the desired forms could be created using a fabrication process (1). It was indicated that vacuum formed polystyrene 'skins' could be used for the majority of the form of the design (1a); whilst conventionally machined components might be inserted for the areas serving as articulating surfaces (1b). Gelutong wood was selected as an appropriate material to make the patterns (2). These patterns were created using established pattern making techniques. 'Core prints' (2a) were added to these intermediate patterns to indicate subsequent cutting lines. The final patterns were assembled using a dichloromethane solvent to weld the polystyrene parts together and an epoxy resin to adhere the machined parts.

Subsequently, the patterns were taken to the Castings Advisory Service, Sheffield for advice on reproducing the patterns in aluminium. Lost wax casting was offered as the most suitable, with the production of the necessary wax components from soft silicone mould tools. Further advice on appropriate materials and methods needed in the manufacture of soft silicone mould tools was sought from an expert model maker at a local cutlery factory. At this stage it became apparent that room temperature vulcanising silicone rubber required a powerful 'degassing' vacuum chamber which had to be constructed. Acrylic mould boxes were made complete with aluminium cores (3a), the boxes were then filled with the silicone rubber. These moulds (3b) were subsequently injected with wax at 1.5bar 70°C. The wax parts (3c) were taken for investment at a local casting firm in low melting point aluminium alloy. The resulting castings (3d) required some subsequent machining and hand finishing (3e).



Development of an Anatomically Analogous Elbow Joint Design Principles

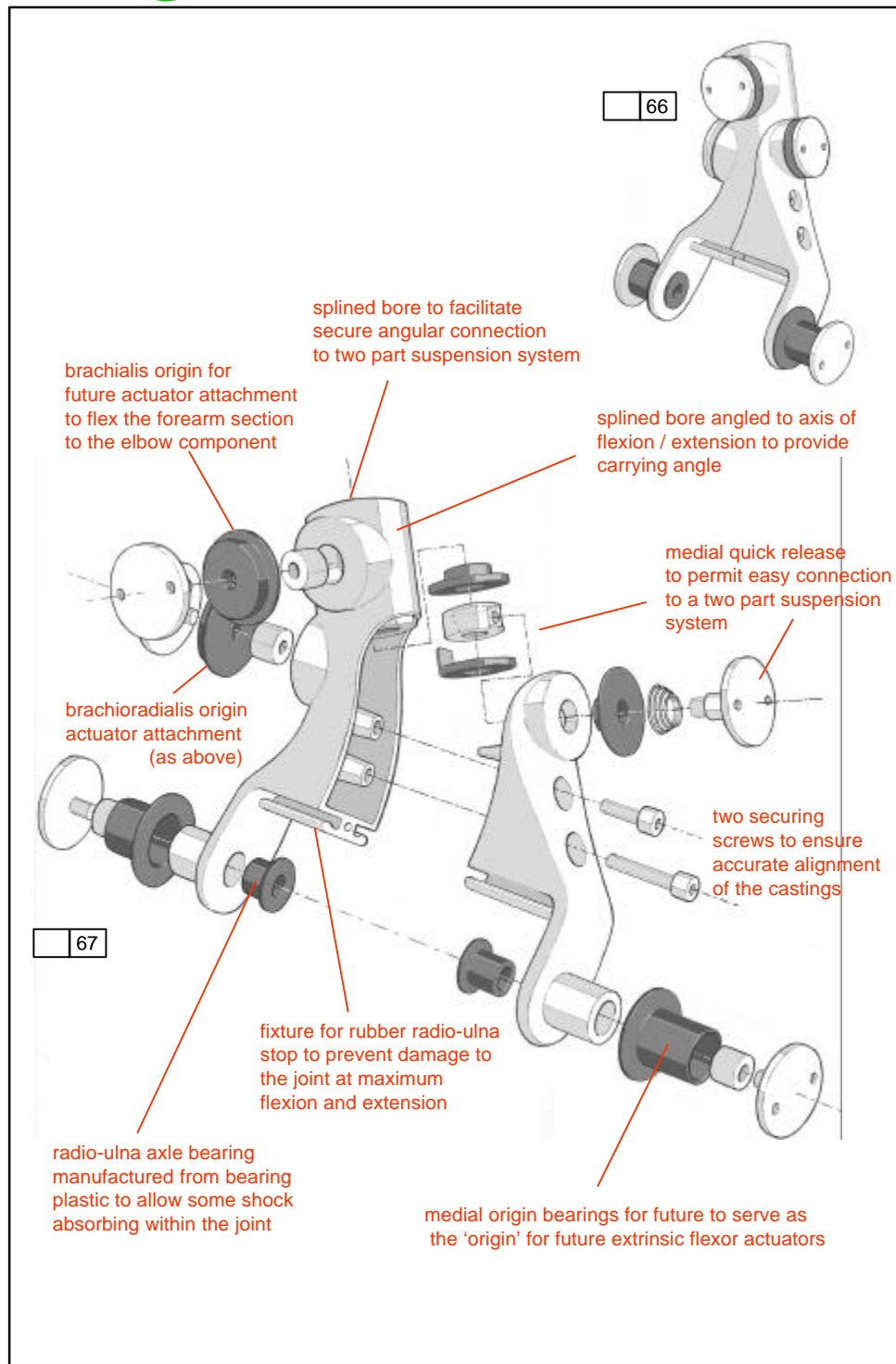


Fig 6.15 Design Principles Embodied Within the Elbow Component

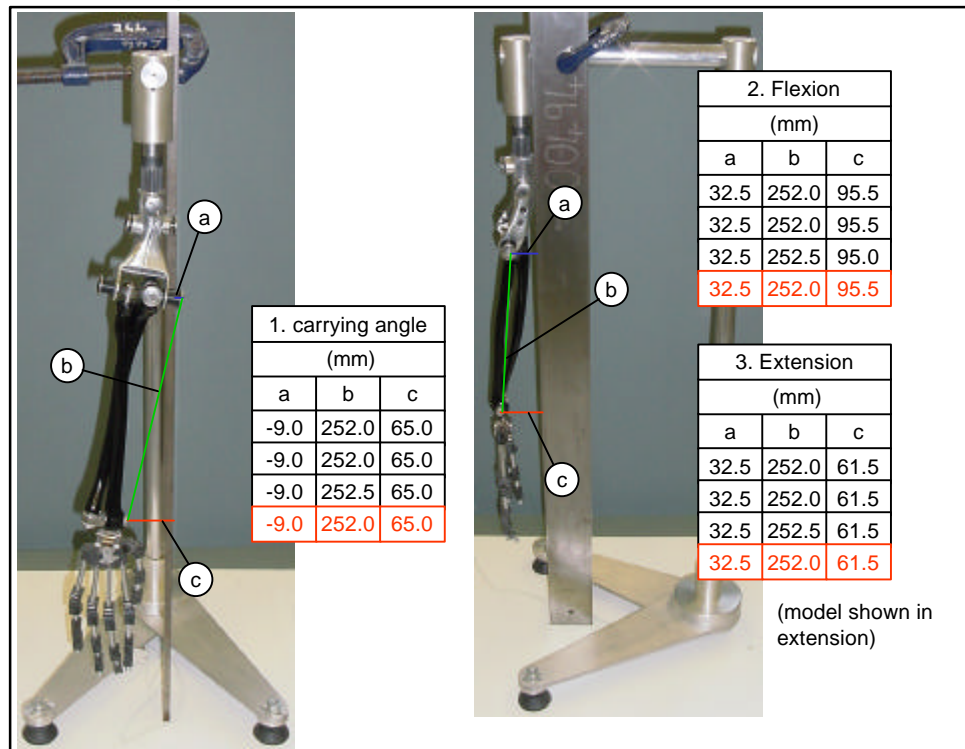
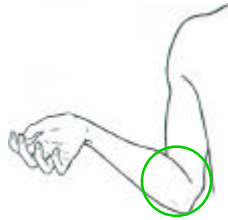


Fig 6.16 Quantitative evaluation

The model arm was secured to a specially made stand through an appropriate splined peg to fit within the splined bore of the elbow component. The peg was aligned with the vertical support of the stand, as was a ground straight edge. Measurements were taken perpendicularly to this edge to determine both the carrying angle of the model in with the model arm in extended position, and the range of flexion and extension of the model.

Using simple trigonometry the carrying angle as defined by Smith et al 1996 was calculated to be:

Carrying angle

$$\sin^{-1}((65.0-9.0)/252.0) = 12.8^{\circ}$$

Range of carrying angle reported in humans 5-19° (Smith et al 1996)

Calculated range of Movement in flexion / extension

Angle to ground edge at full extension

$$\sin^{-1}((61.5-32.5)/252.0) = 6.6^{\circ}$$

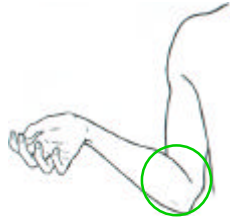
Angle to ground edge at full flexion

$$\sin^{-1}((95.5-32.5)/252) = 14.5^{\circ}$$

Therefore, the range of movement in flexion and extension

$$180-(6.6+14.5) = 159^{\circ}$$

Range of movement in intact human arm 145° (Smith et al 1996)



Qualitative Evaluation of the Model by D. Stanley, Orthopaedic Surgeon

The literature review on the anatomy of the elbow indicates that individual variations in anatomy effect the articulation of the elbow (Kapandji 1982). Additionally, there is uncertainty surrounding whether the elbow possesses fixed or changing carrying angle (Stanley and Kay 1998). Consequently, it was thought appropriate to select a professional with an expert knowledge of the anatomy of the elbow to review the model.

An expert in the field of elbow surgery was identified as D. Stanley an orthopaedic surgeon at the Northern General Hospital, Sheffield. D. Stanley is the co-editor of Surgery of the Elbow: Practical and Scientific Aspects, Arnold 1998 and has an interest in the development of new implantable elbow prostheses.

The forearm and elbow model was taken to the D. Stanley's office at the Northern General Hospital for his review. Present at the evaluation, apart from D. Stanley, were C. Rust and G. Whiteley. D. Stanley's review of the model was documented through notes taken at the time of the evaluation. The evaluation lasted approximately 20 minutes.

Initially, a brief outline of the research aims was given by G. Whiteley. Then the model was presented to D. Stanley for palpation

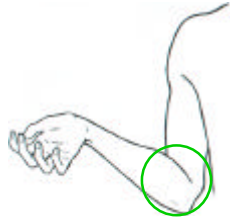
D. Stanley proceeded to palpate the model and view it from multiple angles. His first comments were on the lightness of the model and he inquired as to the materials of its manufacture. From palpation he was content that the range of movement of the model forearm was comparable with that of the human forearm. He indicated that the range of movement in flexion / extension appeared to be greater than normal, however, he added that range of movement at the elbow was also a function of soft tissue, which was absent on the model. He remarked on the possession of a carrying angle in the model, and was content that the single centre of rotation of the model in flexion / extension appeared to feel similar to that of the human elbow.

The remainder of the evaluation indicated he was considering the design as a potential implantable device, although this had not been stated as an aim by G. Whiteley at the start of the evaluation.

On viewing the model from the posterior view he indicated that the linking of the radius and ulna to the humeral (elbow) component was novel. He indicated the principle of linking the radius to the elbow component might have a practical benefit in a future implantable prosthesis. He reported that currently linked prostheses only link the ulna to the humerus, and that common surgical procedure is to excise (remove) the head of the radius. D. Stanley indicated the method of securing the radius to the elbow component through a pin projecting through the centre of the spherical bearing showed a potential principle for an implant using an intermedullary fixing into the radius.

He indicated that if the model elbow was to be used as an implant its form would need to be altered. D. Stanley indicated that 'spaces' that were evident in the model at full extension and were non-existent at full flexion were not appropriate as these 'voids' would eventually be filled by tissue in the body, ultimately limiting the articulation of the joint. Additionally, he indicated that the materials that model was made from were also incompatible with a device fitted inside the body.

The review concluded with D. Stanley expressing an interest to be kept informed on the progress of the research



Discussion

This chapter is distinct from other stages in the design of anatomically analogous joints as it demonstrates that to construct some of the principles for the anatomically analogous model 'speculative reasoning' was needed.

This was necessary in detailing the proximal aspect of the elbow component where suspension of the component from the amputees remaining limb was a factor. Therefore, to develop the proximal form of the component the most successful features of existing suspension systems were considered, resulting in the incorporation of a quick release clip. Additionally, to continue the use of analogy on the distal aspect of the component actuator 'origins' were developed that required communication with specialists involved in the development of novel actuators.

The prototyping methods used were more complex than those used in the development of the finger joints. The use of these methods resulted in a complex model elbow form with a high surface finish. The combination of craft and precision machining processes enabled a complex form to be made that also permitted the articulation of flexion and extension.

The model was reviewed by an elbow surgeon who indicated that the range of movement of the model forearm was what he would expect in a human limb, however, the absence of soft tissue made the comparison of the range of flexion / extension of the model more difficult to assess. Additionally, his evaluation indicated an unexpected potential application for the design principles within the model in the field of elbow implants.